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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,402	06/12/2002	Thierry Marnay	P06794US00/MP	1151
881	7590	10/19/2004	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			MILLER, CHERYL L	
		ART UNIT	PAPER NUMBER	
		3738		

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Jew

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/018,402	MARNAY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2004 and 12 October 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 55-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 55-86 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/25/03</u>	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Response to Arguments/Amendments***

Applicant's arguments with respect to claims 1-65 have been considered but are moot in view of the new ground(s) of rejection.

The declaration under 37 CFR 1.132 filed June 28, 2004 is insufficient to overcome the rejection of claims 55-65 based upon a U.S.C. 103(a) obviousness rejection of Marnay (US 5,314,477) as set forth in the last Office action because: The applicants opinion (the applicant has argued), that it is not obvious to modify the Marnay reference, which has shown the use of two anchors on each end part, to instead have a *single* anchor on each end part. The applicant has argued this is not obvious mainly because at the time the invention was made, it was not known in the art to use a single anchor, that in fact, two anchor were actually *necessary* in order to provide the stability needed to hold the implant in place. The examiner disagrees. A search was conducted and multiple references were found, which disclosed/showed the use of a *single* anchor on end parts of intervertebral implants (see US 4,946,378 US 6,402,785 US 5,507,816 for instance, some of which were cited by the applicant). It is clear that it was well known and feasible in the art at the time the invention was made to use a single anchor to support end parts of intervertebral implants. Therefore, it in fact, would have been obvious to one having ordinary skill in the art as an obvious duplication of parts or an obvious relocation of parts to have fewer or more anchors (such as a single anchor) than the two anchors shown and to place them anywhere along the end parts to provide the necessary support (such as at a midline or line parallel to side surfaces).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64, 66-69, and 73-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 recites the limitation "the shorter sides" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 66 recites the limitation "the tops" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 67 recites the limitation "the rounded portion of the lower part" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 68 recites the limitation "the partially spherical convex surface" and "the top" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 69 recites the limitation "the recess in the lower part" in line 3. There is insufficient antecedent basis for this limitation in the claim. (The recess seems to be in the first piece, not the entire lower part).

Claim 73 recites the limitations "the lower surface of the lower part" and "the short sides" in lines 8 and 9 respectively. There is insufficient antecedent basis for these limitations in the claim. Applicant has not yet claimed a lower surface on the lower part. Claims 74-86 depend upon claim 73 and inherit all problems associated with the claim.

Claim 75 recites the limitations "the said lower surface" and "the upper surface portion" in lines 2 and 3 respectively. There is insufficient antecedent basis for these limitations in the claim. It is suggested to change "the upper surface portion" to --the upper surface--.

Claim 81 recites the limitation "the rounded portion of the lower part" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 82 recites the limitations "the lower surface" and "the top" in lines 2 and 4 respectively. There is insufficient antecedent basis for these limitations in the claim.

It is noted to the examiner, that's claims 58, 59, 76, and 77, each recite, "height of the remainder of their respective parts" and it is unclear what applicant is referring to when they recite the term "remainder" and what the "remainder" is in comparison to (whether applicant is trying to claim the total height of the anchor alone is greater than the height of the part alone, or if the height of the anchor adds to the height of the part, making the part taller).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 55-68, 71, 73-82, and 85 are rejected under 35 U.S.C. 102(e) as being anticipated by Zdeblick et al. (US 6,402,785 B1). Referring to claims 55 and 73, Zdeblick discloses an

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intervertebral implant (10, 110, 240) comprising an upper part (12, 112, 242) having an upper surface (36, 120) for engaging a vertebrae and a lower surface including a rounded portion (fig. 16, 34, 32), a lower part (14+16, 114+116, 244+246) having a lower surface (38, 120) for engaging a vertebrae and an upper surface in engagement with the rounded portion of the upper part (fig. 16, 32, 34), the upper (12, 112, 242) and lower (14+16, 114+116, 244+246) part each having a lead end, which leads as the implant is inserted along a path into the space, and a trailing end opposite the lead end and lateral planes passing through opposed side surfaces of each part and parallel to the path (see figs), and an anchor (18, 19; fewer or greater than ribs shown; col.5, lines 21-28; col.8, lines 53-56; or single rib, 248, 250; col.10, lines 34-40) on the upper surface of the upper part and lower surface of the lower part and located along a line parallel to the path and essentially midway between lateral planes and of a height sufficient to anchor the part into a groove cut into the vertebrae (see figs.16, 32, 34).

Referring to claims 56-68, 71, 74-82 and 85, Zdeblick discloses a lower part comprising two pieces, a lower piece (14, 114, 244) having a recess (see fig.16, 32, 34) and an upper piece (16, 116, 246) having an upper convex partially spherical surface (see fig.16, 32, 34). Zdeblick discloses the recess to have three walls, an end wall, two sidewalls and an opening opposite the end wall (although Zdeblick shows a recess having four walls, the recess still comprises three walls, and the opening exists within the recess, at every parallel location to the one end wall, away from the end wall). Zdeblick discloses an upper part (12, 112, 242) having a concave lower surface (fig.16, 20, 34). Zdeblick discloses anchors (18, 19, 248, 250) to have a sufficient height and length along a path (see figs). Zdeblick discloses the parts in plan view to be generally rectangular (fig.15, 19, 34), and the surfaces of the parts to be spherical (are partially

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spherical in every embodiment, since some embodiments are cylindrical, the parts are spherical in one frontal plane, and in other embodiments, such as in fig.32, 40-42, the parts are completely spherical). Zdeblick discloses apertures (166, 168) in the trailing ends of the parts (fig.23) capable of receiving instruments. Zdeblick discloses teeth on the anchors (barbs, scales, interruptions, col.5, lines 28-33; col.7, lines 13-18).

Claims 55-63, 67, and 73-81 are rejected under 35 U.S.C. 102(b) as being anticipated by Bullivant (US 5,507,816, cited by applicant in IDS). Referring to claims 55 and 73, Bullivant discloses an intervertebral implant (fig.1A, 1B) comprising an upper part (14) having an upper surface (24) for engaging a vertebrae and a lower surface (32) including a rounded portion (fig.3A-3D), a lower part (10+12) having a lower surface (20) for engaging a vertebrae and an upper surface (28) in engagement with the rounded portion (32) of the upper part, the upper (14) and lower (10+12) part each having a lead end, which leads as the implant is inserted along a path into the space (path is along rib and channel), and a trailing end opposite the lead end and lateral planes passing through opposed side surfaces of each part and parallel to the path, and an anchor (22, 26) on the upper surface of the upper part and lower surface of the lower part (fig.2B, 3B) and located along a line parallel to the path and essentially midway between lateral planes and of a height sufficient to anchor the part into a groove cut into the vertebrae (col.3, lines 65-67; col.4, lines 14-16).

Referring to claims 56-63, 67, and 74-81, Bullivant discloses a lower part (10+12) comprising two pieces, a lower piece (10) and an upper spherical convex piece (12; fig.4A-4D). Bullivant discloses the upper part (14) rounded portion (32) to be concave (fig.3A-3D).

Bullivant discloses anchors (22, 26) with sufficient height and length along the path (fig.3A, 3B, 2A, 2D). Bullivant discloses the parts to be generally rectangular (fig.2A, 2E, 3A).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-71 and 73-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay (US 5,314,477, cited by applicant in IDS). Referring to claims 55 and 73, Marnay discloses an intervertebral implant (100) comprising an upper part (110) having an upper surface for engaging a vertebrae and a lower surface including a rounded portion, a lower part (120+20) having a lower surface for engaging a vertebrae and an upper surface in engagement with the rounded portion of the upper part, the upper and lower part each having a lead end, which leads as the implant is inserted along a path into the space, and a trailing end opposite the lead end and lateral planes passing through opposed side surfaces of each part and parallel to the path, and an anchor (1110, 1210) on the upper surface of the upper part (110) and lower surface of the lower part (120+20) and located along a line parallel to the path and essentially midway between lateral planes and of a height sufficient to anchor the part into a groove cut into the vertebrae (fig.1, 3 ). Marnay discloses however, *two* anchors instead of a *single* anchor on each part. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have more or fewer anchors attached to the parts, such as a *single* anchor, (see for instance,

US4,946,378 US6,402,785 and US5,507,816, it is also noted that the applicant has shown in the current application, use of parts with either a single anchor (6) in fig.7 or multiple anchors (6, 7, 7) in fig.6, therefore, the applicant has shown fewer or more anchors are obvious equivalents/modifications) since changing the number of parts, still provides the same function no matter how many of the part are present, this is a matter of mere duplication or change of multiplicity of parts (in this case anchors). In re Harza, 274 F2d 669, 124 USPQ378 (CCPA1960).

Referring to claims 56-71 and 74-85, see figures 1-3.

Claims 55-65 and 67-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al. (US 5,425,773, cited by applicant in IDS) in view of Zdeblick et al. (US 6,402,785 B1). Referring to claims 55 and 73, Boyd discloses an intervertebral implant (110, 410; see figs) comprising an upper part (upper part +socket in figs.) having an upper surface for engaging a vertebrae and a lower surface including a rounded portion (socket), a lower part (lower plate + insert ball) having a lower surface for engaging a vertebrae and an upper surface in engagement with the rounded portion of the upper part (see figs.), the upper and lower part each having a lead end, which leads as the implant is inserted along a path into the space, and a trailing end opposite the lead end and lateral planes passing through opposed side surfaces of each part and parallel to the path, and an anchor (94; col.9, lines 44-46) on the upper surface of the upper part and lower surface of the lower part (fig.6, 14, 22) and located along a line parallel to the path and essentially midway between lateral planes and of a height sufficient to anchor the part into a groove cut into the vertebrae. Boyd discloses however, *multiple* anchors instead of a *single*

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anchor on each part. Zdeblick teaches in the same field of intervertebral implants, that the use of either multiple or single anchors on each part of the implant is sufficient for anchoring into adjacent bone (col.1, lines 60-64; col.5, lines 20-35; col.7, lines 9-18; col.8, lines 53-56; col.10, lines 32-40; fig.15, 34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Boyd's implant having anchors, with Zdeblick's teaching that any number of anchors, including a single anchor, is sufficient to anchor parts into adjacent bone in order to provide an implant with a single anchor on each part having sufficient anchoring ability.

Referring to claims 56-65, 67-72, and 74-86, Boyd discloses a lower part comprising two pieces, a lower piece having a recess with three walls (fig.15, recess comprises three walls), an end wall, two side walls, and an optional opening (fig.18 shows an embodiment eliminating an end wall creating an opening for lateral insertion), and an upper piece with a convex spherical shape (col.8, lines 16-19). Boyd discloses an upper piece having a concave rounded portion, wherein the upper part is capable of nesting within the lower part for a reduced height. Boyd discloses an upper piece of the lower part having a means for snap fitting into the lower piece of the lower part (the means being a clip mechanism, clips creating a snap fit; col.8, lines 55-69).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

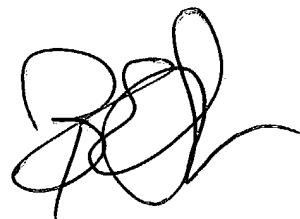
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW  
PRIMARY EXAMINER